



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2017-D-7001]

### Qualified Infectious Disease Product Designation--Questions and Answers; Guidance for Industry; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled “Qualified Infectious Disease Product Designation--Questions and Answers.” The Food and Drug Administration Safety and Innovation Act (FDASIA) created incentives for the development of antibacterial and antifungal drug products that treat serious or life-threatening infections. The purpose of this final guidance is to provide a resource for information on FDA’s policies and procedures related to the designation of a qualified infectious disease product (QIDP). This guidance finalizes the draft guidance of the same name issued on January 30, 2018.

**DATES:** The announcement of the guidance is published in the *Federal Register* on [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

**ADDRESSES:** You may submit either electronic or written comments on Agency guidances at any time as follows:

#### *Electronic Submissions*

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment

does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### *Written/Paper Submissions*

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

*Instructions:* All submissions received must include the Docket No. FDA-2017-D-7001 for "Qualified Infectious Disease Product Designation--Questions and Answers." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT

CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at:

<https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:** Katherine Schumann, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6242, Silver Spring, MD 20993-0002, 301-796-1182, [Katherine.Schumann@fda.hhs.gov](mailto:Katherine.Schumann@fda.hhs.gov).

## **SUPPLEMENTARY INFORMATION:**

### **I. Background**

FDA is announcing the availability of a final guidance for industry entitled “Qualified Infectious Disease Product Designation--Questions and Answers.” Title VIII of FDASIA created the Generating Antibiotic Incentives Now (GAIN) provisions under section 505E of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355f). GAIN offers incentives for the development of antibacterial and antifungal drugs for human use to treat serious or life-threatening infections. The primary incentive contained in GAIN is a 5-year extension of exclusivity for which a QIDP-designated application qualifies upon approval under the FD&C Act. QIDPs also receive fast-track designation at the sponsor’s request (21 U.S.C. 356(b)(1)), and the first marketing application submitted for approval of a QIDP is granted priority review (21 U.S.C. 360n-1).

This guidance provides information about how FDA generally intends to implement GAIN and responses to common questions that might arise about QIDP designation and review of new drug applications for QIDPs.

This guidance finalizes the draft guidance of the same name issued on January 30, 2018 (83 FR 4216). Based on the comments submitted to the docket on the draft guidance, FDA made clarifying changes to this guidance, including further information on what drug products the Agency generally intends to consider to be an antibacterial or antifungal drug for the purposes of QIDP designation. The Agency also provided clarification about when a sponsor should submit a new request for QIDP designation and what information should be included in a QIDP designation request.

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on QIDP designation. It does not establish any rights for any person and is not binding on FDA or the public. You can

use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

## II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 312 have been approved under OMB control number 0910-0014.

## III. Electronic Access

Persons with access to the internet may obtain the guidance at either <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs> or <https://www.regulations.gov>.

Dated: May 5, 2021.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

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